Vaccinia – Adverse Reactions
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Vaccinia
(Adverse Reactions)

Overview[1,2,3]

For a more complete description of Vaccinia, adverse reactions refer to the following texts:

- Centers for Disease Control and Prevention. Smallpox Vaccination and Adverse Reactions, MMWR Dispatch January 24, 2003 / Vol. 52.
- Epidemiology and Prevention of Vaccine-Preventable Diseases 2002, Centers for Disease Control and Prevention (CDC).

The smallpox vaccine currently available in the United States is a live-virus preparation of infectious Vaccinia virus. Smallpox vaccine does not contain smallpox (variola) virus or cowpox virus. Vaccinia is in the same family as cowpox and variola, but is genetically distinct from both, and its exact origin is uncertain.

Epidemiologic studies demonstrated that a high level of protection (95%) against smallpox persists from 3 to 5 years after primary vaccination and substantial but waning immunity for ten years or more. Smallpox vaccine also provides protection if administered after an exposure to variola. The lowest secondary attack rates occurred in persons vaccinated less than 7 days after exposure (NOTE: The optimal time for use of vaccination as a control measure for contacts is administration of vaccine within three days of exposure).

Smallpox vaccine contains live Vaccinia virus, which replicates at the site of vaccination. In addition to a lesion at the site of vaccination, primary vaccination can produce swelling and tenderness of axillary and other lymph nodes, beginning 3 - 10 days after vaccination and persisting for 2 - 4 weeks after the skin lesion has healed. Fever is less common among adults, than in children after vaccination or revaccination. Vaccinia virus is present at the site of vaccination beginning at the time of development of a papule (2 to 5 days after vaccination) and until the scab separates from the skin lesion. Maximum viral shedding from the vaccination site occurs 4 - 14 days after vaccination.

Complications from smallpox vaccination are rare but occur greater than 10 times more often among primary vaccinees than among revaccinees and are more frequent among infants than among older children and adults. Normal reactions to the vaccinia vaccine can include vesicles, pustules and/or induration and itching at the injection site, fever, and head and body aches. In certain groups of people, complications can be severe. People most likely to have adverse reactions are people who have ever been diagnosed with skin conditions (especially eczema or atopic dermatitis) and people with weakened immune systems, such as those who have received a transplant, those who are HIV positive, or those who are receiving treatment for cancer. Pregnant and breast-feeding women should not receive the vaccine, unless they have been exposed to smallpox.

Mild Adverse Reactions

Accidental Administration: Vaccine that is accidentally ingested or inadvertently injected by the intramuscular or subcutaneous route.

Accidental Implantation / (Inadvertent Inoculation): One of the most common adverse events can occur by autoinoculation. Lesions result from the inadvertent transfer of vaccinia vaccine or pustular material to another part of the body of the person receiving the vaccination. Accidental implantation also results from the inadvertent transfer of vaccinia vaccine or pustular material to a close contact of the vaccinee (previously known as **Contact Vaccinia**). *The illness can range from mild to severe.* See Vaccinia Keratitis below.

Bacterial Infections / (Pyogenic infections of vaccination site): The most common organisms are Staphylococcus aureus and Group A Beta Hemolytic Streptococci. Anaerobic organisms occasionally infect the site. Impetiginous vesiculo-pustular lesions are seen in staph infection and piled-up eschar formation is common in streptococcal infections. Mixed infections may be encountered

Erythema Multiforme: Toxic and/or hypersensitivity rashes that occur 1 - 2 weeks after vaccination. The rash varies from erythematous macular lesions, to vesicles, urticaria, pustules and typical bulls-eye lesions, all under the rubric"erythema multiforme". The benign lesions do not progress. Itching may accompany the rash. The most serious reaction, Stevens-Johnson Syndrome (SJS) is rare. Diagnosis is by typical rash seen in temporal association with primary vaccination. The vesicles and pustules do not progress into typical vaccinations and can be distinguished on this basis.

Generalized Vaccinia: Within a week, lesions appear on any part of the body (most often on the trunk and abdomen, less commonly on the face, limbs, palms and soles). Lesions undergo rapid evolution to scarring. Rarely, lesions may recur at 4-6 week intervals for as long as one year. Differentiate from erythema multiforme, eczema vaccinatum, progressive vaccinia, severe chickenpox, and smallpox.

Robust take: Greater than 7.5cm swelling, warmth and pain at vaccination site. Differentiate from Bacterial Infections / (Pyogenic infections of vaccination site).

Tape adhesive reactions: Sharply demarcated raised lines of erythema that correspond to adhesive placement.

Severe Adverse Reactions

Congenital Vaccinia / (Fetal Vaccinia): The third trimester of pregnancy appears to be a critical time for the risk to the fetus of congenital vaccinia, although there have been cases in all trimesters of pregnancy. The affected infant is often premature. The lesions in the newborn infant may be typical of generalized vaccinia or may be progressive in nature. Lesions are often confluent and extensive. Death almost always occurs before birth or shortly thereafter.

Eczema Vaccinatum: Vaccination of individuals with a history of eczema or atopic dermatitis or transfer of Vaccinia virus to individuals with eczema by autoinoculation or from contact with a vaccinee whose lesion is in the florid stages. Because most individuals

have large contiguous patches of eczematous skin in the affected areas, confluent lesions are the rule (on the face and limbs primarily).
Postvaccinial Encephalitis: Onset of headache, vomiting, drowsiness, and fever 10 - 14 days after vaccination. Confusion, ataxia, paralysis, seizures, or coma may be present.
Progressive Vaccinia: Progressive vaccinia is a rare complication occurring primarily in T-cell deficient persons (congenital T-cell deficient children, and those with T-cell deficient diseases such as cancer, immunosuppressive therapy, HIV/AIDS). The primary vaccination fails to heal and spreads locally and by viremia to other parts of the body; each lesion spreads without inflammatory response. Complications include septic shock, disseminated intravascular coagulation, and superimposed microbial infections.
Vaccinia Keratitis / (Ocular Vaccinia): Vaccinia virus can be implanted into diseased or injured conjunctiva and cornea resulting initially in viral replication with ulceration and ultimately in an antigen-antibody interaction leading to corneal cloudiness.

Case Definition [3]

Clinical description
(See table 2 from: Centers for Disease Control and Prevention. Smallpox Vaccination and Adverse Reactions, MMWR Dispatch January 24, 2003 / Vol. 52)

Laboratory criteria:
Viral cultures are needed for suspected Vaccinia, adverse reactions. The State Public Health Laboratory (SPHL) can perform this test. Additional virologic studies may be required to rule out other viral infections with rash, especially chickenpox, herpes simplex, adenovirus, and enterovirus as well as smallpox. The State Public Health Laboratory can perform most of these tests. ***At this time only CDC can perform testing for smallpox***.

Information Needed for Investigation

Verify the diagnosis / Determine the source of infection to prevent other cases. Has the individual or close contact of the person recently received a smallpox vaccination? What laboratory tests were conducted and what were the results?
Establish the extent of illness. Does the case know anyone with similar symptoms? Does the case or a member of the case's household attend school, a childcare center or nursery school? Does the case or a member of the case's household work as a healthcare provider?
Vaccination History. Obtain date of vaccination. What clinic gave the vaccination? What is client's patient's vaccination number (PVN)? Determine if vaccinee or contact of vaccinee is pregnant. If so, notify the Department of Health and Senior Services immediately at **(800-392-0272)**.

Notification and Control Measures:

- **Contact the Senior Epidemiology Specialist for the Region** if a Vaccinia adverse reaction is identified. If possible, obtain written consent (form attached), for a digital photograph to be taken of the adverse reaction. The digital photograph should be submitted with the Vaccine Adverse Event Reporting system (VAERS) form to DHSS.
- Contact the Bureau of Child Care (573-751-2450) if cases are associated with a childcare facility.
- Contact the Section for Long-term Care Regulation (573-526-0721) if cases are associated with a long-term care facility.
- Contact the Bureau of Health Facility Regulation (573-751- 6303) if cases are associated with a hospital or hospital-based long-term care facility.

Control Measures

General:

- The most important measure to prevent "Inadvertent Inoculation" from occurring is thorough handwashing with soap and water after changing the bandage or after any other contact with the vaccination site and/or scab.
- Children who have acquired vaccinia through "Inadvertent Inoculation**"** should be excluded from school or daycare until the lesions are healed.
- Health care workers with adverse reaction should not care for patients until the adverse reaction has resolved.
- Isolation procedures will be forthcoming from CDC for individuals with adverse events requiring hospitalization.

Laboratory Procedure

Specimens: The top of the vesicle or pustule and the base of the vesicle or pustule can be tested for adenovirus, herpes simplex virus, enterovirus, varicella zoster, and vaccinia. Specimen collection and shipping containers are located in the Regional Offices, or may be obtained from the SPHL at (573) 751-0633.

In most instances, differentiation of an adverse event after vaccination from other infectious or non-infectious diseases must be accomplished. In those cases the appropriate diagnostic tests for the alternative diseases, such as chickenpox, should be employed simultaneously with tests for Vaccinia virus. CDC has developed a comprehensive algorithm for the evaluation of rash illness suspected to be poxvirus in origin, located at the following web site: **http://www.bt.cdc.gov/documentsapp/smallpox/rpg/annex/annex-4-rashl-b&w.pdf** (9/03).

Bacterial testing of the site is needed to differentiate between Bacterial Infections / (Pyogenic infections of vaccination site) and Robust take.

Reporting Requirements

Vaccinia adverse reactions are a Category I disease and shall be reported to the local health authority or to the Missouri Department of Health and Senior Services (DHSS) within 24 hours of first knowledge or suspicion by telephone, facsimile or other rapid communication. **DHSS may be contacted 24 hours a day, 7 days a week at (800) 392-0272.**

1. For all cases, complete a "Disease Case Report" (CD-1), VAERS form, and Smallpox Vaccine Adverse Event Follow-Up Form (Annex 4).
2. Entry of the complete CD-1 into the MOHSIS database negates the need for the paper CD-1 to be forwarded to the Regional Health Office.
3. Send the completed secondary investigation form(s) to the Regional Health Office.
4. All outbreaks or "suspected" outbreaks must be reported as soon as possible (by phone, fax or e-mail) to the Regional Communicable Disease Coordinator. This can be accomplished by completing the Missouri Outbreak Surveillance Report (CD-51).
5. Within 90 days from the conclusion of an outbreak, submit the final outbreak report to the Regional Communicable Disease Coordinator.

References

1. U.S. Army Medical Research Institute of Infectious Diseases. Medical Management of Biologic Casualties Handbook. 4th Ed. February 2001.
2. W. Atkinson, C. Wolfe, (Eds.) "Smallpox." Epidemiology and Prevention of Vaccine-Preventable Diseases 7th ed. Centers for Disease Control and Prevention 2002. 230 – 250.
3. Centers for Disease Control and Prevention. Smallpox Vaccination and Adverse Reactions, MMWR Dispatch January 24, 2003 / Vol. 52.

Web Sites

1. **CDC's Smallpox Vaccination and Adverse Events Training Module**
   http://www.bt.cdc.gov/training/smallpoxvaccine/reactions/sitemap.htm (9/03)
2. **USAMRIID's Medical Management of Biological Casualties Handbook**
   http://www.usamriid.army.mil/education/bluebook.html (9/03)
3. **Centers for Disease Control and Prevention**
   http://www.bt.cdc.gov/agent/smallpox/index.asp (9/03)
4. **Centers for Infectious Disease**
   http://www1.umn.edu/cidrap/content/bt/smallpox (9/03)
5. **Department of Health and Human Services**
   http://www.hhs.gov/smallpox (9/03)
6. **Centers for Disease Control and Prevention. Smallpox Vaccination and Adverse Reactions, MMWR Dispatch January 24, 2003 / Vol. 52** (9/03)
7. **Vaccine Adverse-Events Reporting (Annex 4)**
   http://www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-4.pdf (9/03)

TABLE 2. Summary of vaccinia-related adverse events*

Adverse event	Description	Risk factor or predisposition	Treatment
Eczema vaccinatum (EV)	• High fever • Generalized lymphadenopathy with extensive vesicular and pustular eruption • Onset: concurrently or shortly after local vaccinial lesion in vaccinee, or in contacts, 5–19 days after suspected exposure • Risk for secondary bacterial or fungal infections • Virus recovered from lesions • High morality rate with poor prognosis	• History of eczema or atopic dermatitis irrespective of disease activity or severity • Less frequently, persons without a history of dermatological conditions	• Prompt evaluation and diagnosis • Infection-control precautions • Might require multiple doses of vaccinia immune globulin (VIG) (cidofovir, second-line therapy) • Hemodynamic support • Volume and electrolyte repletion • Observe for secondary skin infections
Progressive vaccinia (PV)	• Nonhealing vaccination site • Painless progressive (central) necrosis at the vaccination site • Occasional metastatic lesions in skin, bones, and viscera • No inflammation initially • Absence of inflammatory cells on histopathological examination • Inflammation weeks later • Bacterial infection might develop • Differential diagnosis: severe bacterial infection, severe chickenpox, disseminated herpes simplex, and other necrotic conditions • Prognosis: poor, despite therapy	• Humoral and cellular immunocompromise (e.g., malignancy, human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), severe combined immunodeficiency syndrome (SCIDS), or hypogammaglobulinemia) • Protective level of T-cell count or humoral immunity unknown	• Prompt evaluation and diagnosis • Infection-control precautions • Might require multiple doses of VIG (cidofovir second-line therapy) • Surgical debridement of progressive necrotic lesions not proven useful
Postvaccinial encephalitis (PVE) or encephalomyelitis (PVEM)	• Diagnosis of exclusion • Appears similar to postinfectious encephalomyelitis or toxic encephalopathy caused by other agents • Abrupt onset of symptoms: fever, headache, malaise, lethargy, vomiting, meningeal signs, seizures, paralysis, drowsiness, altered mental status, or coma • Age <2 years (encephalopathy): cerebral vascular changes occurring 6–10 days postvaccination • Age ≥2 years (encephalomyelitis): demyelinating changes occurring 11–15 days postvaccination • Cerebral spinal fluid (CSF): normal or nonspecific; monocytosis, lymphocytosis, or elevated protein • Prognosis: mortality, 25%; neurological sequelae, 25%; complete recovery, 50%	• Age <1 year	• Intensive supportive care • Anticonvulsants as needed • VIG not recommended • Antiviral role unclear • Use of modern imaging studies has not been evaluated
Fetal vaccinia (FV)	• Incidence: rare (<50 reported cases) • Route of transmission: unknown • Outcomes: premature birth, fetal loss, high mortality • Not associated with congenital anomalies	• Cases in all trimesters of pregnancy • Greatest risk, third trimester	• Efficacy of VIG unknown • Antivirals not recommended
Generalized vaccinia (GV)	• Maculopapular or vesicular rash • Onset: 6–9 days postvaccination • Nontoxic, with or without fever • Differential diagnosis: erythema multiforme (EM), varicella, inadvertent inoculation, progressive vaccinia (PV), and smallpox	• Hematogenous spread • Lesions contain vaccinia • More serious among immunocompromised persons	• Usually self-limited in immunocompetent person • Infection-control precautions • VIG usually not indicated • Anti-inflammatory medications • Antipruritic medications • Antivirals usually not indicated

* See text for details.

TABLE 2. (*Continued*) Summary of vaccinia-related adverse events*

Adverse event	Description	Risk factor or predisposition	Treatment
Inadvertent inoculation	• Most common complication • Physical transfer of vaccinia virus from a vaccination site to second site on the vaccinee or to a close contact of vaccinee	• Manipulation of vaccination site • Children aged <4 years • Conditions that disrupt the epidermis (e.g., burns, severe acne, or psoriasis)	• Usually self-limited • Resolution in 3 weeks • Infection-control precautions • VIG if extensive body surface involved or severe ocular disease (cidofovir, second-line therapy)
Ocular vaccinia Inadvertent periocular or ocular implantation with vaccinia virus Can range from mild to severe	Keratitis • Marginal infiltration or ulceration with or without stromal haze/infiltration Conjunctivitis • Hyperemia, edema, membranes, focal lesions, fever, lymphadenopathy Blepharitis • Lid pustules on or near the lid margin, edema, hyperemia, lymphadenopathy, cellulitis, fever	• Manipulation of vaccination site, followed by eye rubbing • More likely with conditions that cause eye itching and scratching (conjunctivitis, corneal abrasion/ulceration)	• Ophthalmologic consultation • Certain ophthalmologists consider off-label topical antiviral medications • Topical prophylactic antibacterial medications for keratitis • VIG for severe blepharitis and blepharoconjunctivitis (without keratitis) • VIG not indicated for isolated keratitis • VIG considered for keratitis with vision-threatening conditions • VIG indicated for keratitis with life-threatening conditions that require VIG
Erythema multiforme (EM) and Stevens-Johnson Syndrome (SJS)	• Typical bull's eye (target) lesions • Hypersensitivity reaction • Pruritis • Onset: 10 days postvaccination • Can progress to SJS	• No known risk factors	• Antipruritic medications • VIG not indicated • Hospitalization and supportive care for SJS • Steroid use for SJS is controversial
Pyogenic infections of vaccination site	• Uncommon • Onset: 5 days postvaccination • Fever not specific for bacterial infection • Fluctuance at vaccination site	• More frequent in children (touching vaccination site)	• Gram stain • Bacterial culture • Antibacterial medications, if clinically indicated • No topical medications
Robust take (RT)	• >7.5 cm with swelling, warmth, and pain at vaccination site • Fluctuant lymph nodes not expected • Peak symptoms: 8–10 days postvaccination • Nonprogressive • Improvement in 24–72 hours	• Might be more likely among first-time vaccinees	• Observation most important • Antibacterial medications not indicated • Rest affected limb • Antipruritic medications • Anti-inflammatory medications • No salves or ointments
Tape adhesive reactions	• Sharply demarcated raised lines of erythema that correspond to adhesive placement • Local pruritis • No systemic illness	• Sensitivity to adhesives	• No salves, ointments, or topical/oral steroids • Frequent bandage changes • Periodic bandage removal

* See text for details.

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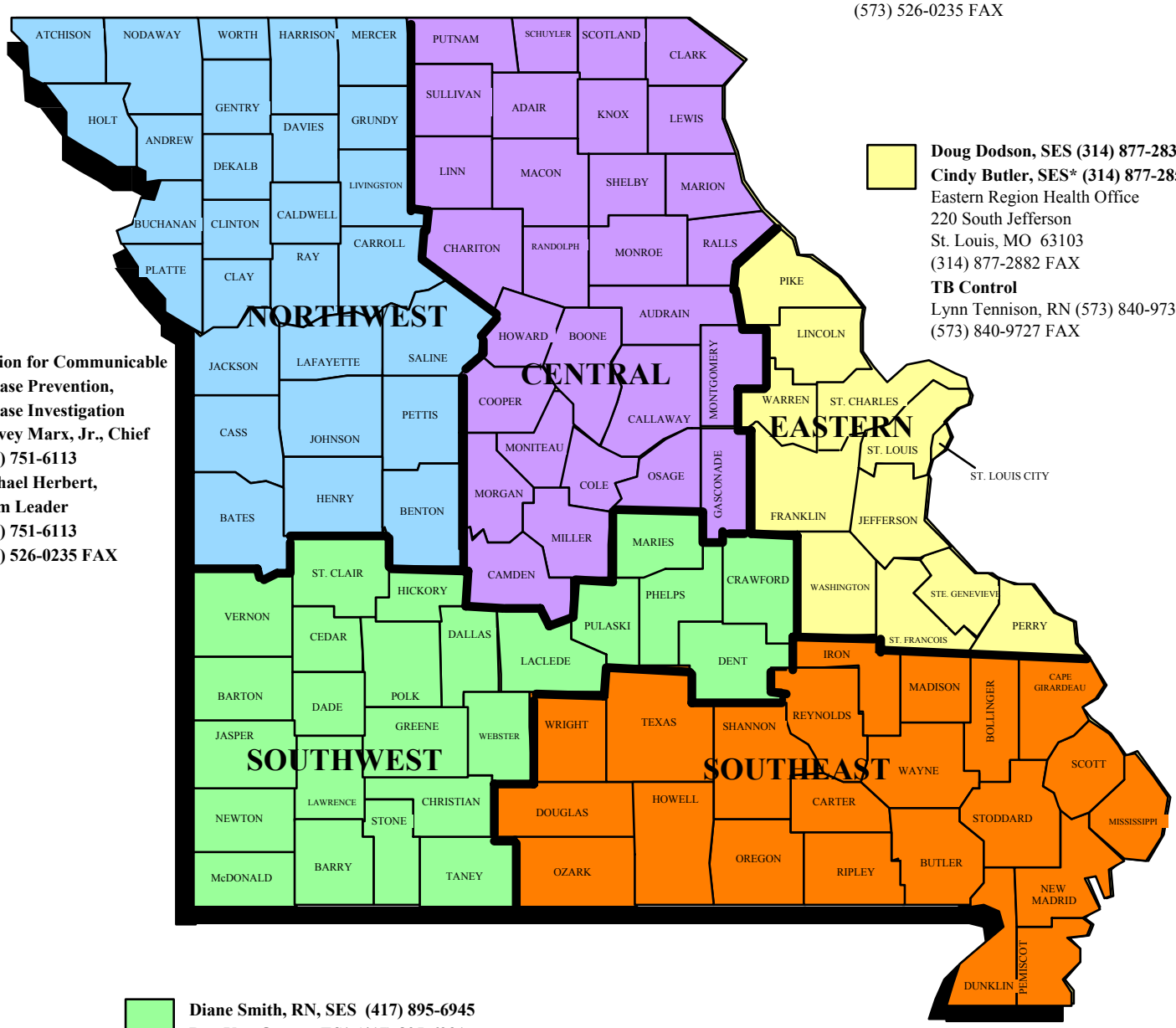

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Asterisk (*) denotes Regional Communicable Disease Coordinator

Return to Vaccinia

SMALLPOX FACT SHEET

Vaccine Overview

The Smallpox Vaccine

The smallpox vaccine helps the body develop immunity to smallpox. The vaccine is made from a virus called *vaccinia* which is a "pox"-type virus related to smallpox. The smallpox vaccine contains the "live" vaccinia virus—not dead virus like many other vaccines. For that reason, the vaccination site must be cared for carefully to prevent the virus from spreading. Also, the vaccine can have side effects (see the section "Smallpox Vaccine Safety" in this fact sheet). The vaccine does not contain the smallpox virus and cannot give you smallpox.

Currently, the United States has a big enough stockpile of smallpox vaccine to vaccinate everyone in the country who might need it in the event of an emergency. Production of new vaccine is underway.

Length of Protection

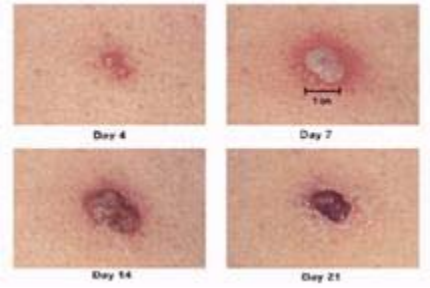
Smallpox vaccination provides high level immunity for 3 to 5 years and decreasing immunity thereafter. If a person is vaccinated again later, immunity lasts even longer. Historically, the vaccine has been effective in preventing smallpox infection in 95% of those vaccinated. In addition, the vaccine was proven to prevent or substantially lessen infection when given within a few days of exposure. It is important to note, however, that at the time when the smallpox vaccine was used to eradicate the disease, testing was not as advanced or precise as it is today, so there may still be things to learn about the vaccine and its effectiveness and length of protection.

Receiving the Vaccine

The smallpox vaccine is not given with a hypodermic needle. It is not a shot as most people have experienced. The vaccine is given using a bifurcated (two-pronged) needle that is dipped into the vaccine solution. When removed, the needle retains a droplet of the vaccine. The needle is used to prick the skin a number of times in a few seconds. The pricking is not deep, but it will cause a sore spot and one or two droplets of blood to form. The vaccine usually is given in the upper arm.

If the vaccination is successful, a red and itchy bump develops at the vaccine site in three or four days. In the first week, the bump becomes a large blister, fills with pus, and begins to drain. During the second week, the blister begins to dry up and a scab forms. The scab falls off in the third week, leaving a small scar. People who are being vaccinated for the first time have a stronger reaction than those who are being revaccinated. The following pictures show the progression of the site where the vaccine is given.

Smallpox vaccination site
Days 4 through 21



Post-Vaccination Care

After vaccination, it is important to follow care instructions for the site of the vaccine. Because the virus is live, it can spread to other parts of the body, or to other people. The vaccinia virus (the live virus in the smallpox vaccine) may cause rash, fever, and head and body aches. In certain groups of people (see the section "Smallpox Vaccine Safety" in this fact sheet), complications from the vaccinia virus can be severe.

Benefit of Vaccine Following Exposure

Vaccination within 3 days of exposure will prevent or significantly lessen the severity of smallpox symptoms in the vast majority of people. Vaccination 4 to 7 days after exposure likely offers some protection from disease or may modify the severity of disease.

Smallpox Vaccine Safety

The smallpox vaccine is the best protection you can get if you are exposed to the smallpox virus. Anyone directly exposed to smallpox, regardless of health status, would be offered the smallpox vaccine because the risks associated with smallpox disease are far greater than those posed by the vaccine.

There are side effects and risks associated with the smallpox vaccine. Most people experience normal, usually mild reactions that include a sore arm, fever, and body aches. However, other people experience reactions ranging from serious to life-threatening. People most likely to have serious side effects are: people who have had, even once, skin conditions (especially eczema or atopic dermatitis) and people with weakened immune systems, such as those who have received a transplant, are HIV positive, are receiving treatment for cancer, or are currently taking medications (like steroids) that suppress the immune system. In addition, pregnant women should not get the vaccine because of the risk it poses to the fetus. Women who are breastfeeding should not get the vaccine. Children younger than 12 months of age should not get the vaccine. Also, the Advisory Committee on Immunization Practices (ACIP) advises against non-emergency use of smallpox vaccine in children younger than 18 years of age. In addition, those allergic to the vaccine or any of its components should not receive the vaccine.

In the past, about 1,000 people for every 1 million people vaccinated for the first time experienced reactions that, while not life-threatening, were serious. These reactions included a toxic or allergic reaction at the site of the vaccination (erythema multiforme), spread of the vaccinia virus to other parts of the body and to other individuals (inadvertent inoculation), and spread of the vaccinia virus to other parts of the body through the blood (generalized vaccinia). These types of reactions may require medical attention. In the past, between 14 and 52 people out of every 1 million people vaccinated for the first time experienced potentially life-threatening reactions to the vaccine. Based on past experience, it is estimated that 1 or 2 people in 1 million who receive the vaccine may die as a result. Careful screening of potential vaccine recipients is essential to ensure that those at increased risk do not receive the vaccine.

Smallpox Vaccine Availability

Routine smallpox vaccination among the American public stopped in 1972 after the disease was eradicated in the United States. Until recently, the U.S. government provided the vaccine only to a few hundred scientists and medical professionals working with smallpox and similar viruses in a research setting.

After the events of September and October, 2001, however, the U.S. government took further actions to improve its level of preparedness against terrorism. One of many such measures—designed specifically to prepare for an intentional release of the smallpox virus—included updating and releasing a smallpox response plan. In addition, the U.S. government ordered production of enough smallpox vaccine to immunize the American public in the event of a smallpox outbreak. Right now, the U.S. government has access to enough smallpox vaccine to effectively respond to a smallpox outbreak in the United States.

For more information, visit www.cdc.gov/smallpox, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)
December 9, 2002

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010

Richard C. Dunn
Director

Bob Holden
Governor

I give permission for _____ to be photographed by a representative of the Missouri Department of Health and Senior Services as part of an epidemiological investigation. The photographs will be treated as a medical record and will not be released to anyone without consent, unless otherwise authorized by law.

Signed _____ Date _____

If signed by someone other than person listed above,

Print name _____

And state relationship _____

Witness signature _____ Date _____

I give permission for _____ to be photographed by a representative of the Missouri Department of Health and Senior Services as part of an epidemiological investigation. The photographs will be treated as a medical record and will not be released to anyone without consent, unless otherwise authorized by law.

Signed _____ Date _____

If signed by someone other than person listed above,

Print name _____

And state relationship _____

Witness signature _____ Date _____

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES

DISEASE CASE REPORT

REPORT TO LOCAL PUBLIC HEALTH AGENCY

1 DATE OF REPORT	**2** DATE RECEIVED BY LOCAL HEALTH AGENCY
_____ / _____ / _____	_____ / _____ / _____

3 NAME (LAST, FIRST, M.I.)	**4** GENDER ☐ MALE ☐ FEMALE	**5** DATE OF BIRTH _____ / _____ / _____	**6** AGE	**7** HISPANIC ☐ YES ☐ NO ☐ UNKNOWN

8 RACE (CHECK ALL THAT APPLY) ☐ BLACK ☐ ASIAN ☐ PACIFIC ISLANDER ☐ WHITE ☐ AMERICAN INDIAN ☐ UNKNOWN	**9** PATIENT'S COUNTRY OF ORIGIN	**10** DATE ARRIVED IN USA _____ / _____ / _____

11 ADDRESS (STREET OR RFD, CITY, STATE, ZIP CODE)	**12** COUNTY OF RESIDENCE	**13** TELEPHONE NUMBER ( )

14 PREGNANT ☐ YES (IF YES NUMBER OF WEEKS _____) ☐ NO ☐ UNKNOWN	**15** PARENT OR GUARDIAN	**16** RECENT TRAVEL OUTSIDE OF MISSOURI OR USA ☐ YES ☐ NO IF YES, WHERE _____	**17** DATE OF RETURN _____ / _____ / _____

18 OCCUPATION	**19** SCHOOL/DAY CARE/WORKPLACE ADDRESS (STREET OR RFD, CITY, STATE, ZIP CODE)

20 WORK TELEPHONE NUMBER ( )	**21** OTHER ASSOCIATED CASES ☐ YES ☐ NO ☐ UNKNOWN IS REPORT PART OF AN OUTBREAK ☐ YES ☐ NO ☐ UNKNOWN	**22** TYPE OF COMPLAINT/OUTBREAK ☐ FOODBORNE ☐ WATERBORNE ☐ OTHER (SPECIFY) _____

23 WAS PATIENT HOSPITALIZED ☐ YES ☐ NO ☐ UNKNOWN	**24** PATIENT RESIDE IN NURSING HOME ☐ YES ☐ NO ☐ UNKNOWN	**25** PATIENT DIED OF THIS ILLNESS ☐ YES ☐ NO ☐ UNKNOWN

26 CHECK BELOW IF PATIENT OR MEMBER OF PATIENT'S HOUSEHOLD (HHLD):	PATIENT			HHLD MEMBER		
	YES	NO	UNK	YES	NO	UNK
IS A FOOD HANDLER						
ATTENDS OR WORKS AT A CHILD OR ADULT DAY CARE CENTER						
IS A HEALTH CARE WORKER						

27 NAME OF HOSPITAL/NURSING HOME	
28 HOSPITAL/NURSING HOME ADDRESS (STREET OR RFD, CITY, STATE, ZIP CODE)	
29 REPORTER NAME	**30** TELEPHONE NUMBER ( )

31 REPORTER ADDRESS (STREET OR RFD, CITY, STATE, ZIP CODE)	**32** TYPE OF REPORTER/SUBMITTER ☐ PHYSICIAN ☐ OUTPATIENT CLINIC ☐ PUBLIC HEALTH CLINIC ☐ HOSPITAL ☐ LABORATORY ☐ SCHOOL ☐ OTHER _____

33 ATTENDING PHYSICIAN/CLINIC NAME ADDRESS (STREET OR RFD, CITY, STATE, ZIP CODE)	**34** TELEPHONE NUMBER ( )

35 DISEASE NAME(S)	**36** ONSET DATE(S) _____ / _____ / _____ _____ / _____ / _____	**37** DIAGNOSIS DATE(S) _____ / _____ / _____ _____ / _____ / _____	**38** DISEASE STAGE/ RISK FACTOR	**39** PREVIOUS DISEASE/STAGE	**40** PREVIOUS DISEASE DATE(S) _____ / _____ / _____ _____ / _____ / _____

41 - DIAGNOSTICS

TEST DATE (MO/DAY/YR)	TYPE OF TEST	SPECIMEN TYPE	COLLECTION DATE (MO/DAY/YR)	QUALITATIVE / QUANTITATIVE RESULTS	REFERENCE RANGE	LABORATORY NAME/ADDRESS (INCLUDE STREET OR RFD, CITY, STATE, ZIP CODE)

42 - TREATMENTS

TREATED (Y/N/UNK)	REASON NOT TREATED	TYPE OF TREATMENT	DRUG	DOSAGE	TREATMENT DATE (MO/DAY/YR)	TREATMENT DURATION (IN DAYS)	PREVIOUS TREATMENT	PREVIOUS LOCATION (LIST CITY, STATE)

43 - SYMPTOMS

SYMPTOM (IF APPLICABLE)	SYMPTOM SITE (IF APPLICABLE)	SYMPTOM ONSET DATE (MO/DAY/YR)	SYMPTOM DURATION (IN DAYS)

44 COMMENTS

NOTES FOR ALL RELEVANT SECTIONS:

- Stages, risk factors, diagnostics, treatments, and symptoms shown below are examples. To see a more complete listing, please go to ***http://www.dhss.state.mo.us/Diseases/DDwelcome.htm***. You may also contact the Office of Surveillance at 1-800-392-0272 for additional information or to report a case.
- All dates should be in Mo/Day/Year (01/01/2001) format.
- All complete addresses should include city, state and zip code.
- Required fields referenced below are italicized and bold, however fill form as complete as possible.

(1) Date of Report -- date sent by submitter of document.

(2) Date received will be filled in by receiving agency.

(3-8) **CASE DEMOGRAPHICS/IDENTIFIERS:** ***Last name, First Name,*** Gender, ***Date of Birth,*** Hispanic, Race - please check all that apply

(23) Was patient hospitalized due to this illness?

(32) Type of reporter/submitter (doctor, nursing home, hospital, laboratory) (33-34) Attending physician or clinic (full physician name and degree, address, phone)

DISEASE: ***(35) Disease name or name(s), (36) Onset date(s), (37) Diagnosis Date(s)***

(38) Disease Stage or Risk Factor

Syphilis	**Gonorrhea or Chlamydia**	**TB Infection**
Primary (chancre present)	Asymptomatic	Contact to TB case
Secondary (skin lesions, rash)	Uncomplicated urogenital (urethritis, cervicitis)	Immunocompromised
Early Latent (asymptomatic < 1 year)	Salpingitis (PID)	Abnormal CXR
Late Latent (over 1 year duration)	Ophthalmia/conjunctivitis	Foreigner/Immigrant
Neurosyphilis	Other (arthritis, skin lesions, etc)	IV Drug/Alcohol Abuse
Cardiovascular		Resident, correctional
Congenital		Employee, correctional
Other		Over 70
		Homeless
		Diabetes
		Healthcare worker
		Converter/2 yrs ≥ 10
		Converter/2 yrs ≥ 15

(39) Previous Disease/Stage (if applicable) ***(40) Previous Disease Dates (if applicable)***

(41) Diagnostics (Please Attach Lab Slip)

Test Type

Hepatitis	**TB**	**Other**
Igm Anti-HBc	Not Done	Elisa
Anti-HBs	Mantoux	Western Blot
Anti-HBc Total	Multiple puncture device	Culture
Igm Anti-HAV	X-Ray	ALT
HBsAg	Smear	AST
Hep C	Culture	

Specimen Type (blood, urine, CSF, smear, swab), **Collection Date** (Mo/Day/Yr), **Qualitative** (negative, positive, reactive), **Quantitative Results** (1:1, 2.0 mm reading,) **Reference Range** (1:1neg, 1:64 equivocal, 1:128 positive, > 2 positive), **Laboratory** (name, address)

(42) TREATMENT

Reason not treated	**Drug**
False positive	**TB**
Previous treated	Isoniazid
Age	Ethambutol
	Pyrazinamide
	Rifampin

(43) SYMPTOMS:

Symptom (jaundice, fever, dark urine, headache) **Symptom Site** (head, liver, lungs, skin), **Symptom Onset Date** (Mo/Day/Yr) and **Symptom Duration** (in days)

(44) **Comments:** Attach additional sheets if more comments needed.

WEBSITE: www.vaers.org E-MAIL: info@vaers.org FAX: 1-877-721-0366

VACCINE ADVERSE EVENT REPORTING SYSTEM

24 Hour Toll-Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only

VAERS Number _____

Date Received _____

Patient Name:

Last First M.I.

Address

City State Zip

Telephone no. (____) _____

Vaccine administered by (Name):

Responsible Physician _____

Facility Name/Address

City State Zip

Telephone no. (____) _____

Form completed by (Name):

Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other

Address *(if different from patient or provider)*

City State Zip

Telephone no. (____) _____

1. State	2. County where administered	3. Date of birth mm / dd / yy	4. Patient age	5. Sex ☐ M ☐ F	6. Date form completed mm / dd / yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
- ☐ Patient died (date mm / dd / yy)
- ☐ Life threatening illness
- ☐ Required emergency room/doctor visit
- ☐ Required hospitalization (_____days)
- ☐ Resulted in prolongation of hospitalization
- ☐ Resulted in permanent disability
- ☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

12. Relevant diagnostic tests/laboratory data

10. Date of vaccination mm / dd / yy Time _____ AM PM

11. Adverse event onset mm / dd / yy Time _____ AM PM

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
- ☐ Private doctor's office/hospital
- ☐ Public health clinic/hospital
- ☐ Military clinic/hospital
- ☐ Other/unknown

16. Vaccine purchased with:
- ☐ Private funds
- ☐ Public funds
- ☐ Military funds
- ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)

20. Have you reported this adverse event previously?
- ☐ No
- ☐ To health department
- ☐ To doctor
- ☐ To manufacturer

Only for children 5 and under

22. Birth weight _____ lb. _____ oz.

23. No. of brothers and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/immunization project

24. Mfr./imm. proj. report no.

25. Date received by mfr./imm.proj.

26. 15 day report? ☐ Yes ☐ No

27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

"Fold in thirds, tape & mail — DO NOT STAPLE FORM"

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE

VAERS
P.O. Box 1100
Rockville MD 20849-1100

DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.

Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.

Item 10 and 11: Give dates and times as specifically as you can remember. If you do not know the exact time, please indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.

Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.

Item 13: List ONLY those vaccines given on the day listed in Item 10.

Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.

Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.

Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.

Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).

Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.

Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.

Item 26: This space is for manufacturers' use only.

Figure 4. VAERS Smallpox Follow-up Form

SMALLPOX VACCINE ADVERSE EVENT FOLLOW-UP

1. VAERS #: _____ 2. Form completed by: _____

MISSING INFORMATION:

Check for missing information on original VAERS form, and obtain if needed.

THIS INFORMATION WAS COLLCTED FROM THE FOLLOWING PERSONS:

3. Name_____ 3a. Name_____

4.Title_____ 4a.Title_____

5. Telephone # ____–_____–____ 5a. Telephone # ____–_____–____

6. Address_____ 6a. Address_____

_____ _____

7. Fax # _____–_____–_____ 7a. Fax # _____–_____–_____

_____

8. E-mail_____ 8a. E-mail_____

_____

9. Date spoken with___/____/___ 9a. Date spoken with___/____/___

CONFIRM VAERS FORM INFORMATION:

10. Patient Name: _____

11. Date of Birth: _____

12. Gender: _____M _____F

13. Update pt's status/VAERS information since the original VAERS form:

MEDICAL HISTORY (has the patient ever had any of the following medical conditions):

14.	Heart disease	□Yes □No	21.	Acquired Immune deficiency (HIV)	□Yes □No
15.	Stroke	□Yes □No	22.	Congenital immune deficiency	□Yes □No
16.	Seizure	□Yes □No	23.	Sickle Cell Disease	□Yes □No
17.	Asthma/emphysema	□Yes □No	24.	Spleen Removal	□Yes □No
18.	Cancer /leukemia	□Yes □No	25.	Automimmune disorder (ex: lupus)	□Yes □No
19.	Eczema	□Yes □No	26.	Hepatitis	□Yes □No
19a.	If yes: Active __ or History of __ (check one)		27.	Frequent/recurrent/severe infections	□Yes □No
20.	Other chronic skin condition	□Yes □No	28.	Other (specify): _____	

29. If you checked "YES" to Cancer/leukemia, other chronic skin conditions, automimmune disorder, or frequent/recurrent/severe infections, please specify what type, when it was diagnosed, and how it was treated:

_____

_____

_____

30. Describe any hospitalizations in the last 1 year (dates, where, why, outcome):

_____

_____

_____

MEDICATION HISTORY:

31. Were you taking any medications at the time of vaccination or since vaccination? □Yes □No
If yes, specify drugs/dates:
32a. Drug_____ 32b. Start dt: ___/___/___ 32c. Stop dt:___/___/___
32d. Drug_____ 32e. Start dt: ___/___/___ 32f. Stop dt:___/___/___
32g. Drug_____ 32h. Start dt: ___/___/___ 32i. Stop dt:___/___/___
33. Allergic to any medications? □Yes □No If yes, specify: _____

VACCINATION HISTORY:

34. Previous vacc with smallpox? □Yes □No □Not sure If yes, when/where: _____
Other vaccines received within 30 days before or after smallpox vaccine:
35a. Vacc1:_____ 35b.Year: ____ 35c. Loc: _____ 35j. Vacc4:_____ 35k.Year: ____ 35l. Loc: ____
35d. Vacc2:_____ 35e.Year: ____ 35f. Loc: _____ 35m.Vacc5:_____ 35n.Year: ____ 35o. Loc: ____
35g. Vacc3: _____ 35h.Year: ____35i. Loc: _____ 35p. Vacc6:_____ 35q.Year: ____ 35r. Loc: ____
36. Have you ever had a serious reaction after any vaccination? □Yes □No
36a. If yes, specify the immunization, the approximate date, the events that occurred, and what was done in response to the reaction:

_____
_____

FEMALES ONLY:

38. Date of LMP___/____/____ 39. Are you currently pregnant? □Yes □No

DETAILS OF ADVERSE EVENT AND MANAGEMENT

40. Which type of adverse event did the patient experience? (check all that apply)
Generalized Vaccinia __
If yes, was it: maculopapular __ vesicular __ unknown __ (check one)
Eczema Vaccinatum __
If yes, describe location(s) of skin involvement:
Progressive Vaccinia (Vaccinia necrosum) __
Post-Vaccinial Encephalitis __
Inadvertant Innoculation __
If yes, involved anatomic area: eye __ mouth __ lips __ genitals __
Other location (describe) _____
Other __
If other, was it: severe local reaction __
bacterial superinfection of vaccination site __
erythema multiforme __
other (describe) _____

41. Which if any of the following were used to treat the patient: (check all that were used)
Vaccinia Immune Globulin (VIG) __
Cidofovir __
Antibiotics __
Other antiviral agents____ If yes, list agent(s):

42. Was the patient hospitalized overnight or for more than one night?
Yes __ No __ Unknown __

43. Was the patient seen or treated in a hospital emergency room or department?
Yes __ No __ Unknown __

44. What is the patient's current recovery status? (check one)
Acutely ill or illness still evolving __
Fully recovered __
Recovered with sequelae __
If yes, please describe: _____
Died __
Unknown __